Remarks

Claims 27-32 are pending and under consideration. Claims 1 and 23-26 were previously canceled, without prejudice against their reintroduction into this or one or more timely filed continuation, divisional or continuation-in-part applications. With this Amendment, Claim 27 is being amended. After entry of this Amendment, claims 27-32 are pending and under consideration. The amendments of the claims and the Office Action mailed December 13, 2007 withdrawing all claims are discussed in more detail below.

I. Statement of Substance of Examiner Interview Under 37 C.F.R. § 1.133(b)

Applicants wish to thank Examiner Susan Ungar for the telephonic interview conducted on 10 January 2008 with Applicants' representatives Susan J. Myers Fitch and Peter J. Dehlinger, in which the Office Action mailed December 13, 2007, withdrawing claims 27-32 from consideration as being directed to a non-elected invention was discussed. The file history was reviewed, and it was agreed that Applicants would submit an Amendment traversing the Action, that the Office should vacate the Action mailed December 13, 2007, and that the prosecution of the present Application should continue.

II. Amendments of the Claims

Claim 27 has been amended for clarity. Support for the amendment is found at least at page 2, lines 22-31 and page 5, lines 29-35 of the specification as filed. No new matter is entered by way of this amendment. Entry of this amendment is therefore respectfully requested.

III. Withdrawal of Claims 27-32 as directed to a non-elected invention

In the Office Action mailed December 13, 2007, the Examiner notes that Applicants' amendment submitted on August 7, 2007 in response to the Office Action mailed February 7, 2007 and the Supplemental Amendment and Statement of the Substance of Examiner Interview submitted on September 25, 2007 are acknowledged and have been entered into the record. However, the Examiner states that she has no record of the interview conducted on September 25, 2007. Thus, Applicants are submitting as evidence for the record, a copy of Applicants' Memo to File, signed and dated September 25, 2007 by Applicants' representative, Euk ("Charlie") Oh. This memo indicates that the Examiner suggested the claim language "induces

an immune response to human PAP," and Claim 27 was amended accordingly in the Supplemental Amendment of September 25, 2007.

In the present Office Action mailed December 13, 2007, the Examiner has withdrawn pending claims 27-32 as being directed to a non elected invention. Applicants traverse.

The Restriction Requirement mailed on September 6, 2006 restricted the claims into two groups. According to the Office, Group 1 (Claim 1) is drawn to an isolated polypeptide which is immunoreactive with an antibody that is itself immunoreactive with SEQ ID NO:2; and Group 2 (Claims 23-26) is drawn to a method of inducing an immune response against human PAP. In a response mailed October 6, 2006, Applicants elected Group 1 with traverse. Applicants' election of Group 1 with traverse was acknowledged in the Office Action mailed February 7, 2007 and the Office reiterated that, if the subject matter of Claim 1 in inventive Group 1 was found allowable, the claims of inventive Group 2 would be rejoined and examined on the merits.

Applicants' Amendment submitted on August 7, 2007 clearly stated that new claims 27 and 28, drawn to an isolated polypeptide immunologically crossreactive with human PAP, wherein the isolated polypeptide comprises at least 90% amino acid sequence identity to SEQ ID NO:2, were based on original Claims 1 and 3 (Group 1) and that new claims 29-32, drawn to a method of inducing an immune response against human PAP in a human subject, were based on original Claims 10-13 (Group 2). The Supplemental Amendment of September 25, 2007 merely changed " immunologically crossreactive" to the Examiner's suggested language "induces an immune response" to human PAP. Thus, Applicants respectfully submit that Claims 27 and 28 are not drawn to a non-elected invention, but are clearly based on the subject matter the Examiner divided into restriction Group 1. The withdrawal of Claims 27 and 28 in the present Office Action mailed December 13, 2007 is clearly in error.

Applicants respectfully request that the presently amended claims, as well as the remarks submitted in the Amendment of August 7, 2007 and summarized below be given their due consideration. Furthermore, Applicants request that, if the subject matter of Group 1 is found allowable, that the claims of inventive Group 2 (i.e., the pending method claims 29-32) be rejoined and examined on the merits.

IV. Brief summary and remarks in response to outstanding rejections

Priority and Antecedent Basis:

The Patent Office contends that prior claim 1 (Group 1) is not adequately supported by the specification of the parent application Serial No. 09/402,845, which allegedly fails to provide

proper antecedent basis for the subject matter of prior claim 1. Applicants disagree and traverse the rejection as applied to claims 27 and 28. As amended, pending claims 27 and 28 (Group 1) are sufficiently supported by the as-filed specification of the parent application and obviate any issues as to priority or antecedent basis.

The specification describes on page 2, lines 26-31 and page 7, lines 29-32 that the isolated polypeptide can comprise a sequence having at least 95% amino acid sequence identity to the sequence identified by SEQ ID NO:2, and such polypeptides can be made by conservative amino acid substitutions, where the conservative substitutions do not alter the sequence by more than 10%. Further, the specification on page 2, lines 23-26 states that the polypeptides can be used as an antigen to produce a humoral and/or cellular response against tumor antigens present in a subject. Inducing an immune response using the claimed polypeptides against human PAP is specifically described throughout the specification, such as on page 3, lines 5-6. Thus, the language used in prior claim 1 and the currently pending claims is found in the instant application such that there is sufficient antecedent basis in the specification for the claims. Reconsideration and withdrawal of the objections is respectfully requested.

Rejection under 35 U.S.C. § 101

Prior claim 1 was rejected under 35 U.S.C. § 101 because the claim is allegedly inoperative and therefore lacking in utility. Applicants traverse the rejection as applied to pending claims 27 and 28.

The rejection for lack of utility rests on a claim construction in which the isolated peptide is a human PAP. However, the specification and original claims clearly provide an isolated polypeptide comprising a sequence having at least 95% amino acid sequence identity to the sequence identified by SEQ ID NO:2, which identifies the sequence of a prostatic acid phosphatase isolated from mouse. The claimed isolated polypeptides are useful in eliciting humoral and cell mediated immune responses against human PAP, a known tumor antigen in prostate cancer. Consequently, the claimed polypeptides have at least one specific, credible and substantial utility. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 101 is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph

Claim 1 was rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. The Patent Office contends that while the specification is enabling for an isolated

peptide of SEQ ID NO:2, it does not enable an isolated variant having at least 90% identity to SEQ ID NO:2.

Claim 1 was rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of adequate written description. The Patent Office contends that a variant having 90% sequence identity to SEQ ID NO:2 does not satisfy the written description standards enunciated in *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and *Enzo Biochem., Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002).

Applicants respectfully traverse these rejections as applied to claims 27 and 28.

1. Enablement

When rejecting a claim under the enablement clause of 35 U.S.C. § 112, first paragraph, the Patent Office bears the initial burden of setting forth a reasonable explanation as to why it believes the scope of protection provided by that claim is not adequately enabled by the description of the claimed invention provided in the specification of the application. *See* M.P.E.P. § 2164.04. In attempting to meet this burden, the Patent Office has construed the claims to require only a single antibody (rather than the genus of antibodies found in a polyclonal antibody) to be cross-reactive with the claimed polypeptide and human PAP, and contends that since an antibody recognizes a minimal epitope size of 5 amino acids, any isolated peptide having 1% identity to SEQ ID NO:2 is encompassed by the claim. This construction is unreasonable and disregards the limitation of the isolated polypeptide being at least 95% identical in amino acid sequence to SEQ ID NO:2. Claims must be viewed in its entirety and requires consideration of all claim limitations in light of and consistent with the written description. *See, e.g., In re Ochai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995). The claimed invention must not be dissected into discrete elements to be analyzed in isolation, but must be considered as a whole. *See WL. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983). When viewed in its proper context, the scope of the claims under examination is directed to an isolated polypeptide that induces an immune response to human PAP, wherein the isolated polypeptide comprises a sequence having at least 95% amino acid sequence identity to the sequence identified by SEQ ID NO:2.

Furthermore, the specification provides a representative embodiment of the claimed polypeptide, namely a prostatic acid phosphatase isolated from mouse, falling within the scope of the claims. This embodiment can induce humoral and cell mediated immunological responses to human PAP as well as cells that express human PAP. As described in the specification, sequences of the human and rat forms of PAP were available to the skilled artisan

at the filing date. The specification states that the amino acid *sequence identity* between human and rat proteins is 78%, between human and mouse is 80%, and between rat and mouse is 87%, emphasizing the high degree of sequence conservation between those mammalian species. Because of this sequence conservation, a person skilled in the art could readily identify sequences conserved between the human PAP and the polypeptide of SEQ ID NO:2 and determine the amino acid residues that can be altered without affecting the immunological crossreactivity of the claimed polypeptide and human PAP. It is submitted in view of the 80% amino acid sequence identity between human and mouse PAP that a person skilled in the art can alter least 20% of the amino acids in the mouse PAP and maintain its immunologic crossreactivity with human PAP, particularly given the position of the Patent Office that an epitope recognized by an antibody is about 5 amino acids. Similarly, in light of the sequence conservation between PAPs, a person skilled in the art can also alter 5% of the amino acids in mouse PAP to have 95% amino acid sequence identity to SEQ ID NO:2 and maintain immunologic crossreactivity with human PAP.

At the filing date of the instant application, the skill in the art for comparing sequences to identify conserved regions were well known and commonly practiced (*see, e.g.,* Altschul *et al.*, 1990, "Basic local alignment tool," *J.Mol. Biol.* 215:403-410). Moreover, the art typically engaged in making variant proteins, such as by introducing mutations into nucleic acids and expressing the mutated nucleic acids in host cells (*see, e.g.*, Ausubel, F.M. *et al.*, 1992, *Current Protocols in Molecular Biology*, John Wiley and Sons, Inc., Media, PA; and Sambrook, *et al.*, 1989, *Molecular Cloning: A Laboratory Manual*, 2nd Ed., Cold Spring Harbor Press, Plainview, N.Y.; which are referenced in the specification on page 1). The references of Roitt *et al* and Bost *et al.* cited in the 103 rejection (see below) also demonstrate that determining immunological crossreactivity between variant proteins was routine in the art. Thus, the skill in the art for making and testing variant proteins was high at the filing date of the instant application.

Given the knowledge and skill in the art, the specification provides sufficient direction to the skilled artisan in which experimentation should proceed, and which experimentation a skilled artisan would consider routine. The specification describes, the types of amino acid substitutions, such as conservative substitutions, that can be made to maintain immunological crossreactivity (page 5, lines 14-21; and page 7 line 28 to page 8, line 6) and provides various exemplary tests for assessing whether the claimed polypeptide can induce an immune response to human PAP (page 14, lines 3-12; and page 16, lines 22-35).

To make a case for alleged unpredictability in the art, the Patent Office asserted the Burgess *et al.* and Lazar *et al.* references, showing that replacement of a single amino acid residue can affect biological activity of the involved peptides. However, these references are not dispositive of predictability for the instant claims. The pending claims recite immunological crossreactivity, while Burgess and Lazar discuss biological function of the specific proteins. Consequently, the findings of Burgess and Lazar do not impact the unpredictability/predictability of the claimed polypeptides to induce an immune response.

In light of the knowledge of other prostatic acids phosphatases, the high level of skill in the art for making and testing variant proteins, the description in the disclosure of an embodiment representative of the claimed polypeptides, and the amount of guidance in the specification, a person skilled in the art can predictably make and use the claimed polypeptides. Because the Patent Office has not advanced sufficient objective evidence to support a case of *prima facie* nonenablement in this case, reconsideration and withdrawal of the rejections under the enablement clause of 35 U.S.C. § 112, first paragraph is respectfully requested.

2. Written Description

Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, complete or partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. *See* M.P.E.P. § 2163; *see also Univ. of Rochester v. G.D.Searle & Co.*, 358 F.3d 916, 69 USPQ2d 1886, 1894-5 (Fed. Cir. 2004).

However, what is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94; *see also Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005) ("The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge. . . As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution.").

In supporting the rejection under the written description clause of 35 U.S.C. § 112, first paragraph, the Patent Office applies the court decisions of *Eli Lilly v. University of California* and *Enzo Biochem., Inc. v. Gen-Probe Inc.* However, subsequent decisions of the Federal Circuit

have modified the application of the holdings in the two court cases. *See Falkner v. Inglis,* 448 F.3d 1357, 79 USPQ2d 1001 (Fed. Cir. 2005) (emphasis added); *see also Capon v. Eshhar,* 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005); *see also see also Invitrogen Corp. v. Clontech Laboratories, Inc.*, 429 F.3d 1052, 77 USPQ2d 1161 (Fed. Cir. 2005).

The holding in *Invitrogen Corp v. Clontech Laboratories, Inc.*, involved claims directed to a reverse transcriptase enzyme lacking RNase H activity. The specification provided a sequence of a deleted form of the enzyme from Murine Maloney Leukemia Virus, whereas the claims covered a broad genus of modified RT enzymes, including those derived from "a retrovirus, yeast, Neurospora, Drosophila, primates, and rodents." *See Invitrogen Corp. v. Clontech Laboratories, Inc.*, 429 F.3d at 1074. The infringer asserted that the claims to the modified enzyme was invalid under the written description clause of 35 U.S.C. § 112, first paragraph because the claims at issue were not limited to sequences recited in the specification. The Federal Circuit, however, upheld the district court's determination of adequate written description, noting the court's determination that "at the time of the invention, sequence of RT genes were known and members of the RT gene *family shared significant homologies* from one species of RT to another and that the sequences for the claimed modified enzymes and other representative RT genes were known" by the critical date. *See id* at 1073 (emphasis added). Even though sequences of the mutant enzymes for the other reverse transcriptases had not been described in the specification, the court emphasized the knowledge available to the public of the sequence of other RT enzymes, such as enzymes from HTLV-1, BLV, RSV, and HIV. The Federal Circuit concluded:

> [T]he shared written description for the patents-in-issue recites both the DNA and amino acid sequences of *a representative embodiment of the claimed RT enzyme.* The specification also discloses test data that the enzyme produced by the listed sequence has the claimed features-DNA polymerase activity without RNase H activity. Under both the *Eli Lilly* and *Fiers* analysis, the specification at bar is sufficient.

See id. at 3d at 1073.

Furthermore, in *Falkner v. Inglis,* 448 F.3d 1357, 79 USPQ2d 1001 (Fed. Cir. 2005), the court stated:

(1) examples are not necessary to support the adequacy of written description;
(2) the written description standard may be met even where actual reduction to practice of an invention is absent; and
(3) there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain recitation of a known structure.

The court noted "where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here "essential genes"), satisfaction of the written description requirement does not require either recitation or incorporation by reference (where permitted) of such genes and sequences." *See id.* at 1366. Moreover, the court held:

> [It] is the binding precedent of this court that *Eli Lilly does not* set forth a *per se* rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, *regardless of whether it is known in the prior art.*

(emphasis added).

In the instant case, the sequence of homologous PAP had been described for several different mammals, including human and rat. The instant specification describes at least a third member isolated from mouse. Again, the amino acid sequence identity between human and rat PAPs is 78%, between human and mouse is 80%, and between rat and mouse is 87%. Given the level of sequence conservation between human, rat, and mouse forms of PAP, a person skilled in the art would have readily discerned the regions conserved between the phosphatases to identify residues that could be altered without affecting the ability of the presently claimed polypeptide to induce an immune response to human PAP. Moreover, as noted above, the assay for polypeptide forms falling within the scope of the claims is straightforward since methods for detecting immunological crossreactivity between proteins were well within the skill of those in the art, as evidenced by the references cited by the Patent Office (*see, e.g.*, Roitt *et al.* and Bost *et al.*, discussed below in the response to the 103 rejection). Applicants provide a working embodiment showing the immunological crossreactivity between the representative example of the claimed isolated peptide and human PAP. Unlike the facts in *Eli Lilly*, Applicants have disclosed a complete structure of a representative isolated polypeptide falling within the scope of the claim, which embodiment elicits an immunological response cross reactive with the human counterpart, and described two other homologs known at the time of the filing of the present application. Furthermore, the presently claimed functional property, *i.e.*, the ability to induce an immune response to human PAP, correlates with the structure of the claimed isolated peptides, which property is particularly relevant in light of the sequence conservation between human, rat and mouse forms. Since the mouse and human PAPs have about 80% sequence identity, a person skilled in the art would readily recognize that at least 20% of SEQ ID NO:2 can be altered and yet still maintain the identity to human PAP and therefore be immunologically crossreactive with the human protein. If forms differing in 20% (i.e., having 80% sequence identity to SEQ ID NO:2) to SEQ ID NO:2 can be readily discerned by the skilled artisan, then a

skilled artisan would be also be able to recognize an isolated polypeptide comprising a sequence having at least 95% amino acid sequence identity to the sequence identified by SEQ ID NO:2 that induces an immune response to human PAP.

Applicants have amply satisfied the written description standard, and respectfully request reconsideration and withdrawal of the rejection under the written description clause of 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 102

Claim 1 was rejected under 35 U.S.C. § 102(e) as being allegedly anticipated by US Patent No. 5,882,864 to An *et al.* ("An *et al.*"), as evidenced by Roitt *et al*, 1993, *Immunology*, Mosby, St. Louis, pgs 6.4-6.5 ("Roitt *et al.*") ; and Bost *et al.*, 1988, *Immunol. Invest.* 17:577-586 ("Bost *et al.*").

Claim 1 was rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Sharief *et al.*, 1992, *Biochem. Biophys. Res. Commun.* 184:1468-1476 ("Sharief *et al.*") as evidenced by Roitt *et al.* and Bost *et al.*

Applicants respectfully traverse the rejections as applied to pending claims 27-32.

The present claims are directed to an isolated polypeptide that induces an immune response to human prostatic acid phosphatase, wherein the isolated polypeptide comprises a sequence having at least 95% amino acid sequence identity to the sequence identified by SEQ ID NO:2.

The Cited Art

AN *ET AL.* provide nucleotide sequences of biomarkers differentially expressed in human prostate cancer, including a marker having approximately 80% sequence identity to SEQ ID NO:2.

ROITT *ET AL.* generally describe antigen-antibody interactions, showing that when two different antigens share a determinant, antibodies that bind to the determinant of one antigen react with the other antigen.

BOST *ET AL.* describes antibodies against a peptide sequence within the HIV envelope protein that also crossreact with human interleukin-2, again exemplifying the concept of common determinants and immune crossreactivity.

SHARIEF *ET AL.* describes the cloning of cDNA encoding *human* prostatic acid phosphatase, the genetic structure, and the amino acid sequence of the enzyme.

The present claims are Novel over the Cited Art

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); *see also* M.P.E.P. § 2131. The identical invention must be shown in as complete detail as it is contained in the claim." *See Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Again, the basis of the rejection rests on the Examiner's interpretation that Applicants are claiming a form of "human prostatic acid phosphatase." This construction of the claim is at odds with the descriptions in the specification and the original claims. Instead, Claim 27 recites "an isolated polypeptide that induces an immune response to human prostatic acid phosphatase, wherein the isolated polypeptide comprises a sequence having at least 95% amino acid sequence identity to the sequence identified by SEQ ID NO:2," and SEQ ID NO:2 identifies a mouse PAP. Thus, the claimed polypeptides do not concern isolated human PAP, which is shown to have about 80% sequence identity to mouse PAP. *See* Specification, page 7, lines 5-10.

The Patent Office contends the phrase "an amino acid sequence of SEQ ID NO:2" includes a subsequence of SEQ ID NO:2 of at least four or five amino acids, and that a "variant having at least 90% identity to the amino acid sequence of SEQ ID NO:2" refers to any subsequence of SEQ ID NO:2 of ten amino acids wherein at least 9 of those amino acids are identical to SEQ ID NO:2." However, the basis for such a claim construction is not found in the language of the specification or originally filed claims, and appears to arise from an asserted common knowledge in the art that an antibody binds to an epitope of 5 amino acids, as well as an extrapolation of "90% sequence identity" as meaning 9 out of a subsequence of 10 amino acids. The examination guidelines, as supported by numerous court decisions, clearly state the impropriety of importing claim limitations that are not part of the claims. *See* M.P.E.P. § 2111.01; *see also In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) ("It was incorrect for the Board to read unwritten limitations into claims 13 and 14, limitations contrary to the plain words of the claims, and contrary to the interpretation that the inventor himself placed on the claims"). Moreover, as emphasized above, the construction is unreasonable since it limits the entirety of the claim based on a single antibody reactive with the claimed polypeptide and human prostatic phosphatase while disregarding other portions of the claim. As such, there is nothing within the language of the claims, or even descriptions in the

specification, to support this meaning given by the Patent Office. The plain meaning of the instant claims refers to an isolated polypeptide that induces an immune response to human prostatic acid phosphatase, wherein the isolated polypeptide comprises a sequence having at least 95% amino acid sequence identity to the sequence identified by SEQ ID NO:2. The claim does not refer to a subsequence of 5 amino acids or 10 amino acids.

As for the cited art references, An *et al.* describes a marker expressed in human prostate cancer, where the marker, according to the Patent Office has about 80% sequence identity to SEQ ID NO:2. The instant claims however, recite an isolated polypeptide that induces an immune response to human prostatic acid phosphatase, wherein the isolated polypeptide comprises a sequence having at least 95% amino acid sequence identity to the sequence identified by SEQ ID NO:2. Given the requirement for identity of the elements for a reference to anticipate a claim, An *et al.* does not anticipate claim 27 or claim 28.

Neither does Sharief *et al.* anticipate the claimed polypeptide since the reference describes human PAP, which, as noted in the instant specification, has 80% amino acid sequence identity to SEQ ID NO:2. Therefore, Sharief *et al.* does not anticipate claims 27 and 28.

Roitt *et al.* and Bost *et al.* are not relevant to the anticipation rejection since they describe crossreactivity of antibodies against common determinants between two proteins but do not show any inherent characteristic not disclosed in An *et al.* or Sharief *et al.* regarding an isolated polypeptide that induces an immune response to human prostatic acid phosphatase, wherein the isolated polypeptide comprises a sequence having at least 95% amino acid sequence identity to the sequence identified by SEQ ID NO:2.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(a).

IX. Conclusion

The presently submitted Amendment is a *bona fide* attempt to advance the application to final action. Applicants respectfully request that the Office Action withdrawing Claims 27-32 be vacated, that the presently amended claims and remarks be given their due consideration, that, if the subject matter of Group 1 is found allowable, the claims of inventive Group 2 (i.e., the pending method claims 29-32) be rejoined and examined on the merits.

If the Examiner believes that any remaining issues are better resolved by a telephone conference, the Examiner is cordially invited to contact the undersigned at 650-838-4422.

No fees beyond those submitted herewith are believed due in connection with this Amendment. However, the Director is authorized to charge any additional fees that may be required, or credit any overpayment, to Perkins Coie LLP Deposit Account No. 50-2207 (Order No. **57636-8013.US01**).

Respectfully submitted,
Perkins Coie LLP

Date: 14 January 2008

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57636-8013.US01/LEGAL13863662.1

Exhibit A

Serial No.: 10/772,856
Attorney Docket No.: 57636-8013.US01

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September 25, 2007

TO: File

FROM: Charlie Euk Oh

RE: **Client-Matter No. 57636-8013.US01**

Examiner Ungar called to suggest possible amendments to claim 27. She thought that the term "immunologically cross-reactive" would make the isolated polypeptide an antibody. However, I informed her that the term is commonly understood by those skilled in the art as referring to a protein that can generate an immune reaction cross reactive to another protein. She suggested, however, that the term might constitute new matter. I didn't reply to that comment, although she was incorrect on that point. I reminded her that the term refers to humoral as well as cell mediated immune responses. After scurrying about for acceptable language, she suggested the amendment in which the isolated polypeptide "induces an immune response to human PAP, wherein the isolated polypeptide comprises at least 90% amino acid sequence identity to SEQ ID NO:1." I indicated that I would present it to the client.

She stated that she would like to get an answer at the latest by end of business day tomorrow and asked that I fax a Supplemental Amendment to the central fax as well as to her fax number 571-273-0837. She suggested that I update her by phone on our decision (571-272-0837).

Charlie Oh 9-25-2007